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Patricia K. Homenes
(Typed or Printed Name of Person Mailing Paper or Fee)

Patricia K. Homenes
(Signature of Person Mailing Paper or Fee)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

SALLBERG et al.

Serial No.: 09/466,035

Group Art Unit: 1635

Filing Date: RCE filed herewith

Examiner: P. Paras, Jr.

Title: COMPOSITIONS AND METHODS FOR TREATING
INTRACELLULAR DISEASES

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. § 1.97

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The information listed below may be material to the examination of the above-identified application. Copies of the information and completed PTO-1449 forms are submitted herewith. The Examiner is respectfully requested to make this information of official record in the application. The information includes:

United States Patent No. 5,589,466 issued December 31, 1996 to Felgner *et al.*;

United States Patent No. 5,766,602 issued June 16, 1998 to Xiong *et al.*;

Barnett, *et al.*, "Vaccination With HIV-1 gp120 DNA Induces Immune Responses That Are Boosted by a Recombinant gp120 Protein Subunit," *Vaccine* 15(8):869-873 (1997);

Butini, *et al.*, "Comparative analysis of HIV-specific CTL activity in lymphoid tissue and peripheral blood," Abstract J 306, *J. Cell. Biochem.*, Suppl. 18B:147 (1994);

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- Cohen, "Jitters Jeopardize AIDS Vaccine Trials," *Science* 262:980-981 (1993);
- Cooney, *et al.*, "Enhanced immunity to human immunodeficiency virus (HIV) envelope elicited by a combined vaccine regimen consisting of priming with a vaccinia recombinant expressing HIV envelope and boosting with gp160 protein," *Proc. Natl. Acad. Sci. USA* 90:1882-1886 (1993);
- Cranage, *et al.*, "Parameters of Protection with Live Attenuated Simian Immunodeficiency Virus," *Journal of Medical Primatology* 24:182-183 abstract 23 (1995);
- Daniel, *et al.*, "High-Titer Immune Responses Elicited by Recombinant Vaccinia Virus Priming and Particle Boosting Are Ineffective in Preventing Virulent SIV Infection," *AIDS Research and Human Retroviruses* 10(7):839-851 (1994);
- Doe, *et al.*, "Induction of Cytotoxic T Lymphocytes by Intramuscular Immunization with Plasmid DNA is Facilitated by Bone Marrow-Derived Cells," *Proc. Natl. Acad. Sci. USA* 93:8578-8583 (1996);
- Fleury, *et al.*, "Memory Cytotoxic T Lymphocyte Responses in Human Immunodeficiency Virus Type 1 (HIV-1)-Negative Volunteers Immunized with a Recombinant Canarypox Expressing gp160 of HIV-1 and Boosted with a Recombinant gp 160," *The Journal of Infectious Diseases* 174:734-738 (1996);
- Fuller, *et al.*, "A Qualitative Progression in HIV Type 1 Glycoprotein 120-Specific Cytotoxic Cellular and Humoral Immune Responses in Mice Receiving a DNA-Based Glycoprotein 120 Vaccine," *AIDS Research and Human Retroviruses* 10(11):1433-1441 (1994);
- Fuller, *et al.*, "DNA Vaccines," *Journal of Medical Primatology* 24(4):182-183 abstract 26 (1995);
- Fuller, *et al.*, "Induction of Immunodeficiency Virus-Specific Immune Responses in Rhesus Monkeys Following Gene Gun-Mediated DNA Vaccination," *J. Med. Primatol.* 25:236-241 (1996);
- Fuller, *et al.*, "Enhancement of Immunodeficiency Virus-Specific Immune Responses in DNA-Immunized Rhesus Macaques," *Vaccine* 15(8):924-926 (1997);

Gorse, *et al.*, "Vaccine-Induced Antibodies to Native and Recombinant Human Immunodeficiency Virus Type 1 Envelope Glycoproteins," *Vaccine* 12(10):912-918 (1994);

Graham, *et al.*, "Augmentation of Human Immunodeficiency Virus Type 1 Neutralizing Antibody by Priming with gp 160 Recombinant Vaccinia and Boosting with rgp 160 in Vaccinia-Naive Adults," *The Journal of Infectious Diseases* 167:533-537 (1993);

Haynes, "Scientific and Social Issues of Human Immunodeficiency Virus Vaccine Development," *Science* 260:1279-1286 (1993);

Haynes, *et al.*, "In Vivo Delivery of HIV and SIV Antigen-Encoding Vectors by Particle Bombardment as an Alternative to Live Recombinant Viruses for the Induction of Humoral and Cellular Immunity," *AIDS Research and Human Retroviruses* 9(1):S75 (1993);

Hu, *et al.*, "Neutralizing Antibodies Against HIV-1 BRU and SF2 Isolates Generated in Mice Immunized with Recombinant Vaccinia Virus Expressing HIV-1 (BRU) Envelope Glycoproteins and Boosted with Homologous gp160," *AIDS Res. Hum. Retro.* 7(7):615-620 (1991);

Hu, *et al.*, "Protection of Macaques Against SIV Infection by Subunit Vaccines of SIV Envelope Glycoprotein gp 160," *Science* 255:456-459 (1992);

Jolly, "Viral Vector systems for gene therapy," *Can. Gene. Ther.* 1:51-64 (1994);

Klaniecki, *et al.*, "Immune response to HIV-1 envelope and core antigens in protection of macaques against chimeric SHIV challenge," *J. Med. Primatol.* 24:182-183 abstract 25 (1995);

McElrath, *et al.*, "Immune Responses Elicited by Recombinant Vaccinia-Human Immunodeficiency Virus (HIV) Envelope and HIV Envelope Protein: Analysis of the Durability of Responses and Effect of Repeated Boosting," *The Journal of Infectious Diseases* 169:41-47 (1994);

Miller, *et al.*, "Targeted vectors for gene therapy," *The FASEB J.* 9:190-199 (1995);

Pialoux, *et al.*, "A Prime-Boost Approach to HIV Preventive Vaccine using a Recombinant Canarypox Virus Expressing Glycoprotein 16 (MN) Followed by a Recombinant Glycoprotein," *AIDS Research and Human Retroviruses* 11(3):373-381 (1995);

Salmon-Céron, *et al.*, "Safety and Immunogenicity of a Recombinant HIV Type 1 Glycoprotein 160 Boosted by a V3 Synthetic Peptide in HIV-Negative Volunteers," *AIDS Research and Human Retroviruses* 11(12):1479-1486 (1995);

Tang, *et al.*, "Genetic Immunization is a simple method for eliciting an immune response," *Nature* 356:152-154 (1992);

Ulmer, *et al.*, "Heterologous Protection Against Influenza by Injection of DNA Encoding a Viral Protein," *Science* 259:1745-1749 (1993); and

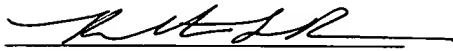
Wang, *et al.*, "Gene Inoculation Generated Immune Responses Against Human Immunodeficiency Virus Type 1," *Proc. Natl. Acad. Sci. USA* 90:4156-4160 (1993).

This Information Disclosure Statement under 37 CFR § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

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Respectfully submitted,

Date: 7/27/01

By: 
Roberta L. Robins
Registration No. 33,208

CHIRON CORPORATION
Intellectual Property - R440
P.O. Box 8097
Emeryville, CA 94662-8097
Telephone: 510-923-2719
Facsimile: 510-655-3542